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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/099,048 06/17/98 NACAMULLI

L KM39091

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EXAMINER

CEPERLEY, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

08/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/099,048

Applicant(s)

NACAMULLI et al

Examiner

Mary E. Ceperley

Group Art Unit

1641



☒ Responsive to communication(s) filed on Jun 2, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

☒ Claim(s) 1-70 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☒ Claim(s) 1-36 is/are allowed.

☒ Claim(s) 37-70 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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1. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

2. The September 28, 1999 response to the November 02, 1998 "Petition to Suspend the Rules Under 37 CFR 1.183" accorded Rule 1.47(a) status to this application.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification ***must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old.*** It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

© In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

5. The specification is objected to under 37 CFR 1.71 because the specification, as originally filed, does not provide an enabling written description of nor support for the invention as it is now

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claimed. The invention as it is described in the specification is limited to a determination of the time course of a biomolecular reaction as set forth in the sequence of reaction steps recited in claims 1-36 of U.S. 5,527,710.

6. Claims 37-70 are rejected under 35 U.S.C. 112, first paragraph, as not corresponding with the enabling written description of the invention as it is set forth in the specification (see paragraph 5. above). The specification, while being enabling for determining the time course of a biomolecular reaction as set forth in the sequence of reaction steps recited in claims 1-36 of U.S. 5,527,710, does not reasonably provide enablement for nor a description of a process comprising simply reacting two members of a specific binding pair in the presence of a luminophore, inducing the luminophore to electrochemiluminesce and measuring the time course of the electrochemiluminescent reaction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to <sup>practice</sup> the invention commensurate in scope with these claims. The invention, *as it is described in the specification*, requires that *three separate reactions* be carried out (pages 6-8 of the specification; claim 1: first reaction: steps (a) and (b); second reaction: steps © and (d); third reaction: steps (e) and (f)) and that an algorithm be applied to compare the resulting electrochemiluminescent "values" for each of the three separate reactions to measure the time course of the biomolecular reaction (claim 1: steps (g) through (k)).

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There is no indication in the specification that the broader concept as is now claimed was contemplated by the inventors. The portions of the specification cited by applicants in their June 02, 2000 response which are argued to support the new generic concept of claims 37-70 do not, in fact, provide such support. Rather the examples are directed to a sequence of enzymatic reactions which corresponds with the sequence of reactions of claim 1 of U.S. 5,527,710.

Further, there is clearly no enablement to support the method of claim 68 wherein *no electrochemiluminescent luminophore is required*. In the absence of a luminophore it would not be expected that electrochemiluminescence would occur upon reaction of any type of "reactant" (e.g. antibody) with its "reaction partner" (e.g. antigen).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 37-70 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the sequence of steps set forth in claim 1 of U.S. 5,527,710.

9. Claims 37-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the following reasons.

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- a. Claims 37, 57 and 68 fail to define what the “reactant” is i.e. what it reacts with.
- b. In claim 37, it is unclear how the “reactant” and “luminophore” interact. Presumably the change in electrochemiluminescence of the “luminophore” is correlated with the formation of the “reaction product” but how this occurs is unclear. To what specific binding moiety is the “luminophore” attached? The same problem exists for claim 62 since it is unclear how the “luminophore” interacts with the enzyme and/or enzyme substrate.
- c. In claims 41 and 42 it is unclear how the “reactant” or “reaction product” “participates with the luminophore in the electrochemiluminescent process”.
- d. Claim 68 inconsistently requires “measuring the electrochemiluminescence” when no electrochemiluminescent moiety is required to be present in the reaction “composition”.
- e. The claims fail to define the relationship between the times at which the composition is exposed to electrical energy and the times at which the electrochemiluminescence is measured (“different” times).
- f. In claim 38, “bimolecular” should be --biomolecular--.

10. Claims 37-39, 40-42, 47, 48, 51-58, 60, 61, and 68 are rejected under 35 U.S.C. 112, first paragraph, as being based on a non-enabling written description for the following reasons.

For these claims, there is an inadequate enabling description in the specification to support the scope of the term “reactant” which would include all types of reactions of organic and/or

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inorganic chemicals and not just reactions between specific binding pair members for which there is enablement in the specification.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 37-39, 41, 42, 49, 51-54, 57, 59, 60, and 68-70 are rejected under 35 U.S.C. 102(b) as anticipated by Shibue et al (WEST abstract of EP500,305A2).

Shibue et al describe a method of measuring an immunoreactant comprising reacting a member of a specific binding pair with its specific binding partner which has been immobilized on insoluble carrier particles and labeled with an electrochemiluminescent label, inducing the label to

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chemiluminesce by activation with electric voltage and measuring the time course of the reaction (i.e. the change in concentration of the immunoreactant). This method anticipates the method of instant claim 37 which involves the same steps as the Shibue et al process.

14. Claims 37-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibue et al (WEST abstract of EP500,305A2) taken in combination with the admitted prior art as set forth in the instant specification.

Shibue et al is applied for the reasons stated in the paragraph directly above. The specific limitations of claims 40, 43-48, 50, 55, 56, 58 and 61-67 constitute obvious modifications of parameters which are admittedly known according to the instant specification, are routinely varied in the art and which have not been described as being critical to the practice of the invention. For example, for the particular ruthenium and osmium luminophores of claims 55 and 56, see the specification at page 18, last paragraph and page 24, third full paragraph; for the equivalence of the use of a variety of specific binding member pairs in the "biomolecular reaction", see the specification at page 16, last paragraph.

15. Claims 1-36 are allowed.



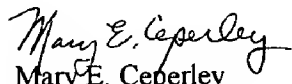
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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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August 08, 2000  
Disk: 06/00

  
Mary E. Ceperley  
Primary Examiner  
Art Unit 1641